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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/543,489	04/06/2000	Pericles Calias	G0651/7023 WGG	7399

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/543,489

Applicant(s)

CALIAS ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,9-21,72 and 74-83 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,81 and 83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,11-21,72,74-80 and 82 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **Final Office Action on the Merits of a RCE**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Status of the Application***

2. Claims 1,2,4,9-21,72 and 74-83 are pending in the present application. Claims 9, 10, 81 and 83 stand withdrawn from further consideration as being drawn to a nonelected invention.

Note: The elected invention is a composition containing EDU and a pharmaceutically acceptable carrier.

#### ***Double Patenting***

3. Claim 82 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 80. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

#### ***Claim Rejections - 35 USC § 112***

4. The rejection of claims 1, 4 and 11-21 under 35 USC 112, first paragraph is maintained and claims 76-79 are rejected under 36 USC 112, first paragraph.

Applicant argues (a) the recitation in the alternative of the neat compound or a pharmaceutical salt implies that the neat compound is neutral and (b) depending on the solvent, the charged or neutral species of the claimed compound will dominate and that said charge species is not separable from an uncharged species. Applicant's argument was considered but not persuasive for the following reason.

The present specification does not define G2 as  $-CN(R_1R_2)$  or  $-N(R_1R_2)$  nor does it make any correlation between a neat compound and a neutral compound. Based on the lack of said disclosure by the present specification and the fact that the chemical art does not recognize a "neat" compound as a neutral compound, the skilled artisan would not readily envision the above-mentioned group based on the present specification. 35 USC 112 requires the claimed invention be described in clear, concise and exact term so that the skilled artisan would recognize that applicant had possession of the claimed invention. The present specification lacks description of the above-mentioned groups in said clear, concise and exact terms.

For this reason and those given in previous Office Actions, the rejection of claims 1, 4 and 11-21 under 35 USC 112, first paragraph is maintained and claims 76-79 are rejected under 36 USC 112, first paragraph.

***Claim Rejections - 35 USC § 102***

**5. The rejection of claim 1 under 35 USC 102(b) over Ito et al. ('151) is maintained.**

Applicant argues Ito lacks express teachings of a pharmaceutically acceptable carrier or a selection of sterile water as such a carrier and that the water utilized by the reference may or may not be pharmaceutically acceptable. Applicant's argument was considered but not persuasive for the following reason.

The instant claim recites "a pharmaceutically acceptable carrier". Water is recognized in the pharmaceutical art as "a pharmaceutically acceptable carrier". The reference teaches a composition comprising EDU and water. Therefore, the claimed invention is anticipated by Ito even though, the reference does not expressly state that the "water" utilized is a pharmaceutically acceptable carrier. Applicant has not provided any factual evidence of record showing "water" as utilized in the prior art composition would not be "pharmaceutically acceptable".

For this reason, the rejection of claim 1 under 35 USC 102(b) over Ito et al. ('151) is maintained.

**6. The rejection of claim 1 under 35 USC 102(b) over Beuvery et al. is withdrawn.**

***Claim Rejections - 35 USC § 103***

**7. The rejection of claims 1, 2, 4, 11-21, 72, 72 and 75 under 35 USC 103(a) over Beuvery et al. is withdrawn.**

**8. The rejection of claims 1, 2, 4, 11-21, 72, 74 and 75 under 35 USC 103(a) over Ito et al. ('151) is maintained and claims 76-80 and 82 are rejected under 35 USC 103(a) over Ito et al. ('151).**

Applicant argues the compositions of Ito lack therapeutic utility and, thus, the skilled artisan would not be motivated to create a tablet, an aerosol or a composition that includes sterile water. Accordingly, applicant states the instant claims satisfy the criteria of *Ruschig* and, thus, are not obvious. Applicant's argument was considered but not persuasive for the following reason.

In *Ex parte Ruschig*, 147 USPQ 46, the Board stated "claim to a tablet used in treatment of specific disease is patentable in view of the nature and recognition of discovery involved, i.e., use of particular substance for the particular purpose". Unlike, the claims allowed by the Board in *Ruschig*, the instant claims do not recite that the claimed formulations, i.e., tablet, aerosol etc., are intended for use in treatment of a specific disease.

For this reason and those given in previous Office Actions, the rejection of claims 1, 2, 4, 11-21, 72, 74 and 75 under 35 USC 103(a) over Ito et al. ('151) is maintained and claims 76-80 and 82 are rejected under 35 USC 103(a) over Ito et al. ('151).

### ***Conclusion***

**9. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


#### ***Telephone Inquiry***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1616

BB  
April 1, 2005